FDA PUBLIC HEALTH NOTIFICATION

Problems with Endovascular Grafts for Treatment of Abdominal Aortic Aneurysm (AAA)

April 27, 2001

Dear Colleague:

This letter is to inform you about serious problems that have occurred with two endovascular prosthetic graft devices used to treat infrarenal AAA, and to make recommendations concerning their continued use. The two products, both of which were approved for marketing in the U.S. in September 1999, are:

Ancure Endograft System (Guidant Endovascular Solutions, Menlo Park, CA) and
AneuRx Stent Graft System (Medtronic AVE, Santa Rosa, CA).

Background

Endovascular repair of AAA is an important new technology. It represents a useful therapeutic option for carefully selected patients whose only previous treatment alternative was open surgical repair of their aneurysm. For patients who are at high risk for adverse outcomes with conventional open surgery, endovascular repair provides an alternative to "watchful waiting." Since this is a rapidly evolving technology, it is critical that physicians who evaluate and treat AAA patients have the information needed to make informed decisions on patient selection, device selection, and follow-up management.

Specific Problems with Endovascular Grafts

The two devices have very different designs, and there are different reasons for the current concerns focused on each.

Ancure system (Guidant)

This device has a flexible, unsupported fabric graft prosthesis that is actively fixed in place on the ends by wire hooks that penetrate the vascular tissue. On 3/16/01, Guidant suspended production and announced a recall of all existing inventory. The company reported to the FDA that they had failed to report many device malfunctions and adverse events, including severe vessel damage associated with problems with the deployment of the device. There were also manufacturing changes that were not properly reported to the FDA. The manufacturer told FDA that an internal audit revealed problems with their complaint handling system, manufacturing quality systems, documentation procedures and training. The FDA is reviewing the firm's Corrective Action Plan that addresses these problems. Once we receive evidence that the firm has appropriately changed their systems and procedures, and the FDA has reviewed their regulatory submissions, we will assess whether the product can be returned to the market.

AneuRx System (Medtronic AVE)

This device has a fabric graft supported along its entire length by a series of metal rings sutured to the graft. The endograft is held in place by the radial force applied by the rings to the patient's aorta. FDA is concerned about reports of approximately 25 aneurysm ruptures, as well as other serious adverse events, in patients who have received AneuRx. Factors thought to be associated with the adverse events, including aneurysm ruptures, include: —sub-optimal placement of the graft; —endoleak (inadequate proximal seal, collateral vessel retrograde flow, persistent perigraft flow); —migration of the main body of the device as well as any attachment cuffs, possibly associated with continuing aortic dilatation; —problems with device integrity, due to metal frame fractures, suture breaks, or fabric tears; and —aneurysm anatomy.

We are working with Medtronic AVE to obtain relevant data that will help us understand how these problems affect the overall risk/benefit assessment of this product.

Recommendations

1. Stay Informed. Endovascular repair of AAA is a new and evolving technology, and both Ancure and AneuRx have undergone changes in design and labeling during the premarket and postmarket phases. Anticipate that there will be changes and improvements as more clinical experience accumulates with this class of devices. We recommend that you carefully follow the device manufacturer's most recent warnings, precautions, and instructions regarding patient selection and device use.
2. Make sure that all implanted patients are carefully followed, and undergo periodic follow-up imaging. Patients who are unlikely to adhere to the manufacturer's graft follow-up recommendations may be poor candidates for endovascular repair, even if they are otherwise suitable. Problems that are identified through follow-up imaging may be amenable to further endovascular repair (e.g. additional stent placement), or might require conversion to open aneurysm resection.
3. Report problems you encounter with the use of these devices, as well as adverse events, to the manufacturer and to the FDA. We will only be able to assess the risk/benefit of these devices, as well as their ultimate clinical usefulness, if we have open communication with practitioners who use them.

Reporting Adverse Events to FDA

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. This means that if a patient death or serious injury can possibly be attributable to an endovascular graft, you should follow the procedures established by your facility for mandatory reporting.

If the stent graft or its delivery system malfunctions, you can report this directly to the manufacturer. Alternatively, you can report directly to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch four ways: online at http://www.accessdata.fda.gov/scripts/medwatch; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Getting More Information

If you have questions regarding this letter, please contact Janet Morgan, R.Ph., Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

All of the FDA's medical device postmarket safety notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html. Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to our list server. You may subscribe at http://list.nih.gov/archives/dev-alert.html.

Sincerely yours,

David W. Feigal, Jr., MD, MPH
Director Center for Devices and Radiological Health Food and Drag Administration